IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

JANE M. HEATHERLY,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-00702

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

Pending before the court are several *Daubert* motions filed by both the defendant and the plaintiff. Briefing is complete regarding these motions, and the motions are now ripe for consideration.

I. Background

This case resides in one of seven Multidistrict Litigations ("MDLs") assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining active MDLs, there are more than 10,000 cases currently pending, approximately 2500 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. The parties have disclosed experts to render opinions regarding the elements of the case's various causes of action, and the

instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431

(4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matter

I begin by addressing a preliminary matter that affects many of the *Daubert* motions. Both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time immemorial," and

therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[1] Likewise, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to apply them in this case. This does not mean that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

[1] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—he or she may not be offered solely as a conduit for corporate information. There is no reason why the plaintiffs require an expert to opine on such facts.

IV. BSC's *Daubert* Motions

BSC seeks to limit or exclude the testimony and opinions of Drs. Niall Galloway, Jimmy W. Mays, Peggy Pence, Richard Wayne Trepeta, and Richard Bercik.

A. Dr. Niall Galloway, M.D.

Dr. Niall Galloway is an Associate Professor of Surgery (Urology) at the Emory University School of Medicine in Atlanta, Georgia. His practice consists largely of handling complications stemming from synthetic mesh placement in the vagina for POP and SUI.

1. Biomaterials

BSC argues Dr. Galloway is unqualified because he stated he is not an expert in biomaterials at his deposition. This testimony, however, is not dispositive. Dr. Galloway is an accomplished urologist with years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. Dr. Galloway's clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction. Accordingly, BSC's motion with regard to Dr. Galloway's qualifications is **DENIED**.

BSC also contends that Dr. Galloway's opinions are unreliable because, at his deposition, Dr. Galloway could not recall whether he reviewed BSC's biocompatibility testing. This does not sufficiently undermine the reliability of his opinions and is an

issue better suited for cross-examination. Accordingly, BSC's Motion with regard to the reliability of Dr. Galloway's biomaterials opinions is **DENIED**.

2. Material Safety Data Sheet ("MSDS")

Next, BSC argues that Dr. Galloway is not qualified to opine on the Medical Application Caution contained in the MSDS for the polypropylene resin used to manufacture the Uphold. Specifically, BSC seeks to exclude two of Dr. Galloway's opinions on this topic:

> (1) I have seen no evidence that Boston Scientific disclosed this information to doctors and patients, nor did Boston Scientific seek further information, or do appropriate testing to determine the validity of these warnings. This is information that doctors and patients are entitled to know and need to know in order to make informed decisions regarding treatment options. Without complete and accurate information, informed consent is not possible.
>
> (2) In my opinion, placing a material that degrades, releases potentially toxic chemicals, creates a chronic inflammatory response, and was advised against by the manufacturers of the raw component represents a serious flaw in the design of Boston Scientific's transvaginal mesh devices.

Galloway Report 9–10. With regard to Dr. Galloway's first opinion, his discussion of BSC's corporate conduct will not be helpful to the jury and is thus **EXCLUDED**. However, Dr. Galloway is qualified, as a physician, to opine that information regarding the Medical Application Caution is critical to the informed consent process.

With regard to the second opinion, Dr. Galloway is not using his "scientific, technical, or other specialized knowledge" to make the factual statement that the manufacturers of polypropylene advised against permanent use, as BSC purports.

Fed. R. Evid. 702. Instead, Dr. Galloway is using the information provided in the Medical Application Caution to support his opinions on the Uphold's design, which, as discussed more fully *supra*, he is qualified to provide. Accordingly, the remainder of BSC's Motion with regard to the MSDS is **DENIED**.

3. Design & Adequacy of Warnings

Next, BSC contends that Dr. Galloway is not qualified to opine on the design or adequacy of warnings of polypropylene transvaginal mesh devices. With regard to design, BSC highlights Dr. Galloway's lack of experience implanting the Uphold or any other polypropylene transvaginal mesh devices. However, Dr. Galloway's experience *removing* polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him in this case. Accordingly, BSC's motion with regard to Dr. Galloway's opinions on product design is **DENIED**.

With regard to warnings, BSC seeks to exclude Dr. Galloway's opinion that alphabetizing the risks in the DFU trivializes certain adverse events. Although Dr. Galloway states that listing complications in order of importance is "convention," he fails to provide any basis for this statement, and the court has no way of assessing its reliability. Accordingly, BSC's Motion with regard to warnings is **GRANTED**, and this opinion is **EXCLUDED**.[2]

[2] To the extent BSC seeks to exclude other warnings opinions, I find that as a urologist, Dr. Galloway is qualified to testify about the risks of implanting the Uphold and whether those risks were adequately expressed in the Uphold's DFU. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (internal quotations and brackets omitted)).

4. Risk/Benefit Analysis

Next, BSC contends that Dr. Galloway provides no factual basis for his opinion that the risks of polypropylene always outweigh the benefits. Drawing on clinical experience and review of relevant literature—which Dr. Galloway has done—is a sufficiently reliable method of forming an opinion that the risks of polypropylene outweigh the benefits. Dr. Galloway's acknowledgement of the mere possibility of a situation where a particular patient might benefit from transvaginal mesh surgery does not undermine his overall opinion, that "for the great majority of patients, the long-term risks do outweigh the benefits." Galloway Dep. 174:11–13, Dec. 17, 2014. Accordingly, BSC's Motion with regard to Dr. Galloway's risk/benefit analysis is **DENIED**.

5. Polypropylene Degradation

Next, BSC challenges Dr. Galloway's degradation opinions objecting to the conclusions that Dr. Galloway makes based on the *Clave* study. Here, Dr. Galloway considered and analyzed multiple scientific articles—not just the *Clave* study—and drew on his clinical experience to reach his opinion that polypropylene degrades. This is a reliable, scientific methodology. Any inconsistencies or discrepancies in his testimony go to its weight, not its admissibility, and BSC is free to capitalize on these matters during cross-examination. Accordingly, BSC's Motion with regard to polypropylene degradation is **DENIED**.

6. Trocars

Next, BSC contends that Dr. Galloway's opinions on trocars, the instrument used to implant certain transvaginal mesh devices, should be excluded because the implantation of the Uphold does not require the use of a trocar. In response, the plaintiffs concede that Dr. Galloway's opinions related to the use of trocars will only be offered if the case involves the use of a trocar. Accordingly, BSC's Motion with regard to trocars is **GRANTED**.

7. Relevant Literature

Lastly, BSC argues that Dr. Galloway's opinions are not tied to the facts of this case because he only reviewed one scientific article that specifically references the Uphold. If there are certain device-specific publications that Dr. Galloway failed to review in preparing his expert report, BSC is free to inquire about those publications on cross-examination. Accordingly, BSC's Motion with regard to literature is **DENIED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. [ECF No. 29] is **GRANTED in part** and **DENIED in part**.

B. Dr. Jimmy W. Mays, Ph.D.

Dr. Jimmy Mays is a Distinguished Professor of Chemistry at the University of Tennessee who offers general causation opinions on the following issues: (1) the chemical structure and properties of polypropylene; (2) degradation of polypropylene

by thermo-oxidative processes and in vivo; and (3) the effect of in vivo degradation on the polypropylene implant.[3]

BSC argues that Dr. Mays's opinions should be excluded because his thermogravimetric analysis ("TGA") did not replicate the in vivo environment. Dr. Mays produced certain results while testing polypropylene at very high temperatures. He then concluded that the same results will occur inside the human body at much lower temperatures, but he did not provide any explanation or support for his opinion. These derivative conclusions are not the product of reliable principles and methods. Dr. Mays failed to demonstrate a reliable connection between his TGA results and his conclusions about polypropylene degradation in the human body. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [ECF No. 33] is **GRANTED**, and Dr. Mays's general causation opinions based on his TGA are **EXCLUDED**.

C. Dr. Peggy Pence, Ph.D., RAC, FRAPS

Dr. Peggy Pence is a clinical and regulatory consultant who provides advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the FDA.

[3] As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these objections are or attach the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Gido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

1. Qualifications

BSC maintains that Dr. Pence's work as a researcher and consultant on the development of medical products does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. Dr. Pence has over forty years of experience in the research and development of medical devices. Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, I **FIND** that Dr. Pence is qualified to render the opinions set forth in her expert report.

2. General Objections

I begin by addressing two objections that BSC raises multiple times throughout its motion, all related to the reliability of the authoritative sources underlying Dr. Pence's opinions, which include a 2006 study by the French National Authority for Health ("HAS"), the recommendations of the National Institute for Health and Care Excellence ("NICE"), and the various guidance documents drafted by the Global Harmonization Task Force ("GHTF").[4] BSC has not cited any case suggesting that the binding effect of industry standards dictates their reliability. Indeed, the Seventh Circuit Court of Appeals has suggested the opposite:

[4] The GHTF, which was conceived in 1992 and replaced by the International Medical Device Regulators Forum ("IMDRF") in 2011, represented a partnership between regulatory authorities and regulated industry and sought to achieve greater uniformity between national medical device regulatory systems. The European Union, United States, Canada, Australia, and Japan were the founding members, and these entities, as well as Brazil, China, Japan, and Russia, currently form the Management Committee of the IMDRF. Dr. Pence relies on several GHTF "Final Documents" in reaching her opinions.

> [T]he relevant question for admissibility purposes is not whether the . . . guidelines are controlling in the sense of an industry code, or even how persuasive they are. It is only whether consulting them is a methodologically sound practice on which to base an expert opinion in the context of this case.

Lees v. Carthage Coll., 714 F.3d 516, 525 (7th Cir. 2013). Accordingly, I give no import to the nonbinding nature of the HAS, NICE, and GHTF recommendations in my *Daubert* analysis and instead focus on whether Dr. Pence's reliance on these sources constitutes a methodologically sound practice.

BSC also attempts to equate GHTF standards with FDA regulations and asserts that, like FDA regulations, admission of GHTF standards, which have "regulatory purpose, history, and focus," could confuse and mislead the jury. GHTF standards do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. Although the FDA appears to have had a limited role in the activities of the GHTF, that role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA. Accordingly, I **FIND** BSC's argument without merit.

3. Premarket Testing

Generally, BSC contends that none of the studies Dr. Pence relies on support her opinion that BSC should have performed premarket clinical trials. My review of the exhibits, however, indicates that several guidance documents supply a basis for this opinion. Additionally, although the NICE and HAS studies are not as explicit as the GHTF documents, they both emphasize the importance of clinical trials in

assessing a product's safety for surgical use. Furthermore, all of these documents carry the indicia of reliability set forth by *Daubert*: the conclusions were reached after documented and validated testing, the results were published, and the testing was conducted through a defined methodology described in each paper. Therefore, I **FIND** Dr. Pence's consultation of these sources in reaching her opinion both justified and reliable.

Next, BSC argues that Dr. Pence's report lacks a discussion of the GHTF standard itself and how Dr. Pence's application of that standard led her to form the opinions contained in her report. These remaining arguments go to the weight of Dr. Pence's testimony, not its reliability, and are therefore better suited for cross-examination. In conclusion, I **DENY** BSC's Motion to exclude Dr. Pence's opinion on premarket clinical testing.

4. Product Labels

BSC asserts that to the extent Dr. Pence's opinions on product labeling relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), they should be excluded. I agree. As I have held several times in the course of these MDLs, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the state tort claims than enlightenment. I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim"). These opinions are **EXCLUDED**.

This finding, however, does not result in the exclusion of Dr. Pence's opinion on product labeling altogether because, unlike in previous cases, Dr. Pence has a second source of information that is unrelated to the FDA (i.e., the GHTF's *Label and Instructions for Use for Medical Devices*), which I must also consider in my analysis. The GHTF document on product labels does not state—expressly or otherwise—that manufacturers should include the severity, frequency, and permanency of adverse events in a warning, nor does it state that a label should qualify the difficulty of removing the device. Furthermore, Dr. Pence does not explain how this document could be interpreted as such. Seeing no non-FDA grounds for Dr. Pence's opinion that BSC should have included this particular information in its labels, I **FIND** it unreliable, and it is therefore **EXCLUDED**.[5]

With respect to Dr. Pence's remaining opinions on product labeling, BSC moves for exclusion because Dr. Pence never spoke to any physicians about this issue. An expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert* so long as the expert has other "sufficient facts or data" to support her opinion. Fed. R. Evid. 702. Here, Dr. Pence considered the GHTF's *Label and Instructions for Use for Medical Devices*, the DFU, several BSC internal documents, and other medical and scientific literature. I find this collection of sources sufficient for the purposes of *Daubert*. BSC has ample grounds to cross-examine and impeach Dr. Pence at trial regarding any perceived oversights in her analysis.

[5] BSC raises this objection only to Dr. Pence's opinions that the label should have included information on the difficulty of mesh removal and the permanency, severity, and frequency of adverse events. My holding is therefore limited to these specific opinions as well.

5. Post-Market Vigilance

In arriving at her post-market vigilance opinions, Dr. Pence exclusively considered data from the FDA's MAUDE database.[6] As I have previously explained, BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database has "no bearing on whether BSC provided adequate warnings or whether its products were defective." *Sanchez*, 2014 WL 4851989, at *36. Any opinion based on data collected in the MAUDE database, which acts as an arm of the FDA, is not helpful to the jury and is therefore inadmissible. *See* Fed. R. Evid. 702 (stating that the expert's specialized knowledge must "help the trier of fact to understand the evidence or to determine a fact in issue"). Because Dr. Pence's opinion on post-market vigilance appears to be entirely based on data—or lack thereof—found in the MAUDE database, I find it unreliable. Without a reliable basis, Dr. Pence's opinion on BSC's inadequate post-market vigilance is **EXCLUDED**, and BSC's Motion on this matter is **GRANTED**.

6. Carcinogenicity of Polypropylene

Finally, BSC argues that Dr. Pence's opinions regarding the carcinogenicity of polypropylene mesh must be excluded as unreliable, irrelevant, and prejudicial. The plaintiff does not respond to this argument. Therefore, BSC's Motion on this point is **GRANTED**.

---

[6] "The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." FDA, *MAUDE—Manufacturer and User Facility Device Experience*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm (last visited April 3, 2016).

7. Final Caveat: Relevance

BSC argues that several of the standards Dr. Pence relies on were not published until after the device at issue was marketed, making those standards irrelevant to this case. I **RESERVE** ruling on this matter until trial.

In sum, BSC's Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [ECF No. 39] is **GRANTED in part, DENIED in part**, and **RESERVED in part**.

D. Dr. Richard Wayne Trepeta, M.D.

Dr. Richard Trepeta is a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease.

1. Qualifications

First, BSC objects to Dr. Trepeta's opinion testimony on the properties of polypropylene mesh. Given Dr. Trepeta's knowledge and experience as an anatomical and clinical pathologist, I find him qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC's Motion in this respect.

Second, BSC objects to Dr. Trepeta's testimony on the human clinical response to mesh implants. Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through clinical and pathologic correlation. Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. Dr. Trepeta's

understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response. Therefore, I **DENY** BSC's Motion as to Dr. Trepeta's qualifications on this point.

2. Reliability and Relevance

BSC raises two objections to the reliability and relevance of Dr. Trepeta's opinion testimony.

a. Reliability

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion: (1) he has studied over fifty mesh explant samples in his private practice; (2) he has studied the medical literature on mesh implantation and determined that his pathological findings corresponded with the published research on mesh erosion and exposure in the vaginal wall; and (3) he has reviewed twenty-four pathology reports that he received from the plaintiffs' counsel and ascertained that the pathology reports of excised Boston Scientific products are consistent with the acute, sub-acute, and chronic categories of the disease process.

Dr. Trepeta's review of the pathology reports has a fatal deficiency—it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. The plaintiffs do not explain how or why they chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. Accordingly, Dr. Trepeta's opinions derived solely from his review of the twenty-four pathology reports are

EXCLUDED. BSC is free to cross-examine Dr. Trepeta at trial to ensure the basis of his opinions is consistent with the court's ruling.

b. Litigation Driven

BSC argues Dr. Trepeta's opinions are unreliable because they are litigation driven. I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. BSC's Motion is **DENIED** on this point.

In conclusion, Dr. Trepeta's general causation opinions are admitted except for his opinions based on the pathologic reports selected by the plaintiffs' counsel for his review, which are excluded. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Dr. Trepeta [ECF No. 43] is **GRANTED in part** and **DENIED in part**.

E. Dr. Richard Bercik, M.D.

Dr. Richard Bercik is urogynecologist and surgeon with extensive experience using polypropylene mesh products.

1. Polypropylene Properties

BSC argues that Dr. Bercik is not qualified to offer opinions regarding stiffness, porosity, bridging fibrosis, scar-plate formation, or degradation because Dr. Bercik is not a biomaterials expert. Dr. Bercik has performed over 2000 surgeries implanting POP and SUI mesh devices, and he has performed over 250 surgeries removing pelvic floor synthetic mesh. The plaintiff concedes that Dr. Bercik will not be asked to provide chemical explanations regarding stiffness, porosity, etc. Instead, the plaintiff states that Dr. Bercik's opinions will not go beyond reporting the clinical effects Dr. Bercik has seen in his practice and review of the scientific literature. I

FIND that Dr. Bercik is qualified to discuss these matters as it relates to his clinical experience. BSC's Motion is **DENIED** on this point.

2. Labeling Opinions

Next, BSC argues that Dr. Bercik's opinions on the adequacy of its Directions For Use ("DFU") should be excluded because they were not disclosed in his expert report and because he is unqualified to offer them. In response, the plaintiff points out that Dr. Bercik only offered his opinions on the DFU during his deposition in response to a question by BSC's counsel. Therefore, I assume that he does not intend to offer these opinions at trial, unless he is again asked by BSC's counsel. Accordingly, I **RESERVE** ruling on this issue until trial.

3. Degradation

BSC next argues that Dr. Bercik's opinion that polypropylene degradation has occurred in the plaintiff is not helpful to a jury because Dr. Bercik did not personally examine the plaintiff's mesh explant, but instead relied on a pathology report from another expert. Rule 703 of the Federal Rules of Evidence states, "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need to be admissible for the opinion to be admitted." I **FIND** that Dr. Bercik may reasonably rely on expert pathology reports to assist him in forming his opinion. BSC's Motion on this point is **DENIED**.

4. Specific Causation

BSC argues that Dr. Bercik's specific causation opinions should be excluded as unreliable; however, BSC raises concerns for opinions relating to four plaintiffs—none of whom is the plaintiff in this case. Accordingly, BSC's Motion is **DENIED** on this point.

In sum, BSC's Motion to Exclude the Testimony of Dr. Bercik, M.D. [ECF No. 38] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part.**

V. The Plaintiff's *Daubert* Motions

The plaintiff seeks to limit or exclude the testimony and opinions of Drs. Roger Goldberg, Christine Brauer, Patrick Culligan, Stephen Spiegelberg, and Stephen F. Badylak.

A. Dr. Roger Goldberg, M.D.

Dr. Roger Goldberg is the Director of the Division of Urogynecology at NorthShore University HealthSystem and an Associate Professor of Obstetrics and Gynecology at the University of Chicago Pritzker School of Medicine. He is a member of the board of directors for the American Urogynecologic Society and is the co-inventor of the Uphold.

1. Conflict of Interest

First, the plaintiff argues that Dr. Goldberg is biased in favor of the Uphold because he invented it and because he testified that he has been paid approximately $1.4 million from BSC since 2005. I find such an argument unavailing under *Daubert*.

Bias and witness credibility are appropriate topics for cross-examination. The plaintiff's Motion with respect to this matter is **DENIED**.

2. Personal Experience

Next, the plaintiff argues that Dr. Goldberg's opinions on the Uphold's safety should be excluded as unreliable because they are based solely on his personal experience. I disagree. *Daubert* permits an expert to rely heavily on his experience to form opinions. Even so, Dr. Goldberg's relied-upon list plainly reveals that he also considered scientific literature in forming his opinions. I decline to impose a blanket exclusion on all of Dr. Goldberg's safety opinions on the reasoning that they are based on his personal experience. The plaintiff's Motion with respect to this matter is **DENIED**.

3. Complication Rate

The plaintiff argues that Dr. Goldberg's opinion that the complication rate for the Uphold is less than three percent should be excluded because it is based on a calculation of cases at his medical center and is not supported by any scientific studies. However, it does appear to be supported by scientific studies—specifically, Dr. Goldberg's data was published by a peer-reviewed journal. *See* Manhan K. Vu et al., *Minimal Mesh Repair for Apical and Anterior Prolapse: Initial Anatomical and Subjective Outcomes*, 23 Int. Urogynecol. J. 1753, 1753–61 (2012). Accordingly, I find the plaintiff's challenges without merit, and the Motion as to complication rates is **DENIED**.

4. Physical Properties of Polypropylene

The plaintiff first challenges Dr. Goldberg's qualification to opine on the physical properties of mesh because he is not a materials scientist, biomedical engineer, or a pathologist and admits as much. However, his extensive clinical experience surgically treating pelvic floor disorders with mesh, as well as his review of and contributions to the medical and scientific literature adequately qualify him to opine on polypropylene. Accordingly, the plaintiff's Motion as to Dr. Goldberg's qualifications is **DENIED**.

The plaintiff also challenges the reliability of Dr. Goldberg's opinion on the physical properties of mesh—specifically that the device in question does not degrade, contract, or encapsulate. Dr. Goldberg claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon relevant medical and scientific literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Goldberg has based his opinions on his extensive clinical experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Goldberg did not observe evidence of mesh contraction because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Goldberg reviewed an extensive list of literature in forming his opinions generally,

the court is directed to minimal specific support for the statements at issue or detail about Dr. Goldberg's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

5. Response to Plaintiff's Experts' Claims

Lastly, the plaintiff argues that all of Dr. Goldberg's opinions in response to the plaintiff's experts' claims should be excluded because he is not qualified and his method was unreliable. Specifically, the plaintiff objects to Dr. Goldberg's opinions on (1) vaginal mesh implantation, (2) the MSDS, and (3) the severity of complications in the DFU.

a. *Vaginal Mesh Implantation*

The plaintiffs challenge the reliability of Dr. Goldberg's opinion stating that the plaintiff's experts are wrong that bacteria in the vagina make transvaginal mesh surgery inadvisable—specifically that polypropylene does not become routinely infected. Dr. Goldberg claims he based this opinion on his clinical experience, during which he did not encounter mesh infection, and upon peer-reviewed literature. This opinions presents the same challenges to assessing the reliability as those discussed above. For the reasons discussed at length in my analysis of Dr. Goldberg's opinions on the physical properties of polypropylene, I am without sufficient information at

this time to determine the reliability of his opinions on mesh infection. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

b. MSDS

The plaintiff argues that Dr. Goldberg is unqualified to opine as to the MSDS for polypropylene mesh. The opinions to which the plaintiff refers are not expert opinions. Thus, I need not address them under *Daubert*. The plaintiff's Motion with respect to this matter is **DENIED**.

c. DFU

Dr. Goldberg does not provide the court the basis of his opinion relating to the DFU, so the court cannot conclude that it was the result of a reliable methodology. *See Daubert*, 509 U.S. at 590 ("Proposed testimony must be supported by appropriate validation . . . ."). Dr. Goldberg's opinion is therefore **EXCLUDED** as unreliable.

Accordingly, as set forth above, the plaintiff's Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [ECF No. 31] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

B. Dr. Christine Brauer, Ph.D.

Dr. Christine Brauer is the President of Brauer Device Consultants LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements.

The plaintiff seeks to exclude both of Dr. Brauer's expert reports filed on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory

framework for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a medical device must meet. I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. Accordingly, the plaintiff's Motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiff contends that it is nothing more than her FDA report under a different cloak. I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. This "industry standard" clearly describes the FDA 510(k) process, which Dr. Brauer admits in her deposition. There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiff's Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 34] is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety.

C. Dr. Patrick Culligan, M.D.

Dr. Patrick Culligan is a urogynecologist offering general causation opinions related to polypropylene products generally and BSC's Uphold device in particular.

1. Safety and Efficacy

First, the plaintiff challenges the reliability of Dr. Culligan's opinion that the Uphold is safe and effective to treat POP because Dr. Culligan acknowledged that there are only four scientific studies addressing the Uphold. She also contends that Dr. Culligan may not reliably base his Uphold opinions on studies about other POP products without detailed knowledge of how the products compare. I find these arguments unavailing because Dr. Culligan based his opinions on scientific literature, including a published study that he conducted on the Uphold. *See* Culligan Report Ex. B.

Similarly, the plaintiff challenges the reliability of Dr. Culligan's opinion that the Uphold is safer and more effective than traditional non-mesh POP procedures because of the lack of studies making this comparison.[7] However, Dr. Culligan's method is not unreliable just because a direct comparison study does not exist between these treatments.

Next, the plaintiff argues that Dr. Culligan may not reliably consider his personal experience in forming his opinions because Dr. Culligan could not testify as to exact statistics about his patients. However, such detail is not required under *Daubert* to opine as to the large-scale safety and efficacy of the relevant device.[8]

---

[7] BSC contends in its response that the plaintiffs do not challenge this opinion. Upon my reading of the plaintiffs' motion, I disagree.

[8] The plaintiff also challenges an opinion that Dr. Culligan asserts at his deposition—that the complication rate in his patients implanted with the Uphold is one percent. However, this opinion is not within Dr. Culligan's report. Thus, I must presume that Dr. Culligan does not plan to offer it at trial, and I need not assess the reliability of it.

The plaintiff also points to a comment made during Dr. Culligan's deposition to argue that he failed to account for contrary literature in forming his opinions. I am satisfied that Dr. Culligan followed a reliable methodology in reaching his opinions on the safety and efficacy of the Uphold device, notwithstanding the deposition testimony. Furthermore, I decline to address Dr. Culligan's opinion on shrinkage here. The plaintiff brings a separate challenge to such opinions, which is addressed below. In summary, the plaintiff's Motion as to Dr. Culligans's safety and efficacy opinions is **DENIED**.

2. Physical Properties of Polypropylene Mesh

The plaintiff challenges the reliability of Dr. Culligan's opinion on the physical properties of mesh, including the nonoccurrence of shrinkage, foreign body response, and degradation. Dr. Culligan claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon peer-reviewed literature. On the one hand, these are reasonable bases from which to form an expert opinion. On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations or the methodology. Further, I have no basis to assess claims that Dr. Culligan's observations are supported by the scientific community/literature.

For the reasons discussed at length in my analysis of Dr. Goldberg, I am without sufficient information at this time to determine the reliability of Dr. Culligan's opinions on the physical properties of mesh. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

3. Mesh Design

Next, the plaintiff contends that Dr. Culligan is not qualified to opine as to the mesh design process. I agree. Dr. Culligan testified at his deposition that he has not designed any POP products, and the court is unpersuaded by BSC's argument that Dr. Culligan has sufficient experience with pelvic floor repair kits to opine as to the Uphold design. Dr. Culligan's opinions on this matter are **EXCLUDED**.

4. DFU

The plaintiff also argues that Dr. Culligan is unqualified to opine as to the Uphold DFU. Based on a demonstrated lack of knowledge as to DFUs and an admitted lack of expertise in the area, the court finds insufficient indicia of Dr. Culligan's qualification to opine on DFUs. His opinions on the DFU are **EXCLUDED**.

5. MSDS

I decline to entertain the plaintiff's challenge to Dr. Culligan's opinions concerning the MSDS because the parties agreed as to the parameters of his testimony on this matter at Dr. Culligan's deposition. The parties agreed that Dr. Culligan could testify that "[he] didn't know what an MSDS sheet was and that 'he'd never consulted one." Culligan Dep. 171:19–23, Jan. 12, 2015. Thus, the plaintiff's Motion with respect to Dr. Culligan's MSDS opinions is **GRANTED**.

6. Patient Brochure

Although the plaintiff argues that Dr. Culligan's opinions on any patient brochures should be excluded, BSC concedes he will not offer such opinions at trial. Thus, the Motion with respect to this matter is **DENIED as moot.**

7. Opinions on FDA

Although the plaintiff argues that Dr. Culligan's opinions concerning the FDA should be excluded, BSC concedes he will not offer such opinions at trial. Thus, the motion with respect to these opinions is **DENIED as moot**.

In sum, the plaintiff's Motion to Exclude Certain Opinions and Testimony of Dr. Culligan [ECF No. 32] is **GRANTED in part**, **DENIED in part**, **DENIED as moot in part**, and **RESERVED in part**.

D. Dr. Stephen Spiegelberg, Ph.D.

Dr. Stephen Spiegelberg is the president and co-founder of Cambridge Polymer Group Inc., where he directs a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer industries.

1. Position Statements

First, the plaintiff argues that Dr. Spiegelberg's opinions regarding position statements should be excluded because (1) they are not contained in his expert report; (2) he is not qualified to offer such opinions; and (3) he lacks any reliable methodology. Upon review, I agree with BSC that Dr. Spiegelberg does not in fact offer the opinions the plaintiff seeks to exclude. Accordingly, the plaintiff's Motion with regard to position statements is **DENIED as moot**.

2. FDA

Next, the plaintiff contends that Dr. Spiegelberg is unqualified to opine on the FDA 510(k) clearance process and that such opinions should be excluded as irrelevant. In response, BSC concedes that Dr. Spiegelberg will not offer opinions on

the FDA 510(k) clearance process. Accordingly, the plaintiff's Motion with regard to the FDA is **DENIED as moot.**

BSC limits its concession by arguing that Dr. Spiegelberg is qualified to opine on International Organization for Standardization ("ISO") standards based on his experience in the field of medical device analysis and design. I agree. Dr. Spiegelberg's current work revolves around medical device development and consultation. He is also the Task Force Chairman for the American Society for Testing and Materials ("ASTM"), which establishes standards involving the cleanliness of biomedical devices and characterization methods for polymers. Consulting on the development of new medical products requires familiarity with the applicable industry standards. Therefore, to the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiff's Motion with regard to Dr. Spiegelberg's qualifications is **DENIED**.

3. Black Specks or Spots

Next, the plaintiff argues that Dr. Spiegelberg's opinions regarding black specks in BSC's mesh are unfounded and unreliable. In his expert report, Dr. Spiegelberg states that the "black spots" are actually reflections of light on the curves of the mesh when pictures are taken, rather than inclusions or defects in the mesh. The plaintiff contends that Dr. Spiegelberg's findings are unreliable because he did not review the photographs supplied by a plaintiff's expert, Dr. Dunn, nor did he take his own photographs. Whether Dr. Spiegelberg took his own photographs does not

sufficiently undermine the reliability of his analysis here. Challenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black spots are better suited for cross-examination. Accordingly, the plaintiff's Motion with regard to black specks or spots is **DENIED**.

4. FTIR and EDS

Finally, the plaintiff seeks to limit Dr. Spiegelberg's general causation opinions based on his Fourier Transform Infrared Spectroscopy ("FTIR") and Electron Dispersive Spectroscopy ("EDS") testing. However, the plaintiff points out that Dr. Spiegelberg's admissions regarding the limitations of these testings may also be grounds for cross-examination and thus seeks only qualification or explanation of the limitations inherent to the testing in order to avoid misleading or confusing the jury. The plaintiff will have the opportunity to adequately highlight these limitations at trial upon cross-examination. Accordingly, the plaintiff's Motion with regard to Dr. Spiegelberg's FTIR and EDS testing is **DENIED**.

In sum, the plaintiff's Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 45] is **GRANTED in part**, **DENIED in part**, and **DENIED as moot in part**.

E. Dr. Stephen F. Badylak, D.V.M., Ph.D., M.D.

Dr. Stephen Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a tenured professor with the Department of Surgery at the University of Pittsburgh.

1. Risk-Benefit Analysis or Safety and Efficacy

The plaintiff contends that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and he has no clinical experience using these devices. Dr. Badylak's expert report indicates that he reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. Furthermore, Dr. Badylak explains that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.

Similarly, the plaintiff's arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. Accordingly, the plaintiff's Motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

2. Lack of Correlation Between Microscopic Findings of Explanted Mesh and Clinical Symptoms

Next, the plaintiff seeks to exclude Dr. Badylak's opinions noting a lack of correlation between microscopic findings of explanted mesh with clinical symptoms such as dyspareunia. I **FIND** that Dr. Badylak's opinions on this point are based on

a reliable methodology. If the plaintiff feels that Dr. Badylak failed to consider certain literature to the contrary, she can address this purported shortcoming on cross-examination. The plaintiff's Motion on this point is **DENIED**.

3. Degradation

Finally, the plaintiff argues that Dr. Badylak's opinions with regard to oxidative degradation based on the scientific literature are unreliable because he contradicted himself during his deposition by acknowledging the "phenomenon" of oxidative reactions. However, the plaintiff omits Dr. Badylak's subsequent testimony, where he states that he does not believe that oxidative reactions at the surface of polypropylene results in the degradation that causes further problems. Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiff's Motion with regard to degradation is **DENIED**.

The plaintiff's Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 47] is thus **DENIED**.

VI. Effect of *Daubert* Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VII. Conclusion

For the reasons stated above, my rulings on BSC's *Daubert* motions are as follows: the Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. [ECF No. 29] is **GRANTED in part** and **DENIED in part**; the Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [ECF No. 33] is **GRANTED**; the Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [ECF No. 39] is **GRANTED in part, DENIED in part**, and **RESERVED in part**; the Motion to Exclude the Opinions and Testimony of Dr. Trepeta [ECF No. 43] is **GRANTED in part** and **DENIED in part**; and the Motion to Exclude the Testimony of Dr. Bercik, M.D. [ECF No. 38] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part.**

For the reasons stated above, my rulings on the plaintiff's *Daubert* motions are as follows: the Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [ECF No. 31] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**; the Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 34] is **GRANTED**; the Motion to Exclude Certain Opinions and Testimony of Dr. Culligan [ECF No. 32] is **GRANTED in part**, **DENIED in part**, **DENIED as moot in part**, and **RESERVED in part**; the Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 45] is **GRANTED in part**, **DENIED in part**, and **DENIED as moot in part**; and the Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 47] is thus **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: August 9, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE